

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: NEW ENGLAND
COMPOUNDING PHARMACY,
INC. PRODUCT LIABILITY
LITIGATION**

**MDL NO. 13-md-2419
Master Dkt.: 1:13-md-02419**

Hon. F. Dennis Saylor, IV

This Document Relates To: All Cases.

**MOTION OF OBJECTOR SOUTHEAST MICHIGAN SURGICAL
HOSPITAL TO QUASH PLAINTIFFS' SUBPOENA *DUCES TECUM* AND
TO PARTICIPATE IN JULY 18 CONFERENCE BY TELEPHONE**

Respondent and Objector Southeast Michigan Surgical Hospital

("Respondent" or "the Hospital") requests this Court to quash in its entirety the Subpoena *Duces Tecum*, issued to Respondent by Plaintiffs' Steering Committee on or about June 21, 2013. Respondent filed its Notice of Limited Appearance [DOCKET #235] and its Objection [DOCKET #236] on July 3, 2013. This Motion supplements that Objection. This Motion is brought under Federal Rule of Civil Procedure 45(b) and 45(c), and is supported by an accompanying Memorandum.

Respondent also requests that its counsel be permitted to attend the upcoming July 18 Status Conference by telephone, in a manner consistent with this Court's Standing Order on the subject.

Counsel for Respondent wrote to Plaintiffs' counsel, the issuer of the Subpoena, in an initial attempt to confer in good faith about the foundation for the

Subpoena. Respondent's counsel requested information that would render relevant the documents sought by the Subpoena. That letter went by email and US Mail. Plaintiffs' counsel had not responded to that letter by the morning of July 15.

On the morning of July 15, 2013, counsel for Respondent also telephoned Mr. Lipton and, in a second phone call the same day, Mr. Sickels (who is working on the discovery in Michigan) to confer before filing this motion. Although both conversations were polite, professional, and open, it is clear from the discussion that the objections raised by Southeast Michigan Surgical Hospital could not be resolved without resolution by this Court.

Respectfully submitted,

DYKEMA GOSSETT PLLC

By: /s/ Kathryn J. Humphrey
Kathryn J. Humphrey
Michigan Bar No. P32351
Attorneys for Southeast Michigan Surgical
Hospital
400 Renaissance Center
Detroit, MI 48243-1668
(313) 568-6848
khumphrey@dykema.com

Dated: July 15, 2013

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MEMORANDUM OF LAW IN SUPPORT OF
MOTION OF OBJECTOR SOUTHEAST MICHIGAN SURGICAL
HOSPITAL TO QUASH PLAINTIFFS' SUBPOENA *DUCES TECUM*
AND TO PARTICIPATE IN JULY 18 CONFERENCE BY TELEPHONE

Pursuant to Rule 45(c) of the Federal Rules of Civil Procedure, Respondent and Objector Southeast Michigan Surgical Hospital ("the Hospital") seeks an Order quashing the Subpoena *Duces Tecum*, dated June 21, 2013. **Not one of the Hospital's patients is part of the fungal meningitis outbreak**, and the Subpoena issued to the Hospital has no relevance to any claims that are or could be a part of this Multi-District Litigation. The facts and the law compel the conclusion that, as to this Hospital, the Subpoena ought to be quashed.

I. FACTS SPECIFIC TO RESPONDENT

The Hospital and Its Use of NECC Product. Southeast Michigan Surgical Hospital is not a party to this litigation. The Hospital, located in Warren, Michigan (10 miles north of downtown Detroit), is a specialty surgery hospital with 20 in-

patient beds, 3 operating rooms, and an additional procedure room. It was established in 2003. The Hospital also trains podiatric surgeons, offering a residency program that sends highly-trained podiatrists to other hospitals and facilities in Michigan. It offers procedures in spinal, vascular, orthopedic, podiatric, gastro-intestinal and general surgery; it performs procedures such as spinal reconstruction and fusion, laminectomy, arthroscopic and endoscopic surgery of the foot and ankle, limb salvage, vascular access surgery, procedures needed for the treatment of gastro-intestinal diseases like chronic ulcerative colitis, and diagnostic procedures like colonoscopy and biopsy.

The Hospital purchased **one shipment** of methylprednisolone acetate (“MPA”) from New England Compounding Pharmacy. Most of that shipment had not yet been administered by the time of the recall notice issued by NECC. Each of those patients who received a steroid injection was contacted by certified mail, in order to make them aware of the significance of the recall, the symptoms of meningitis, and the importance of contacting their health care provider if they are concerned in any way about symptoms or their condition. Anyone concerned about symptoms (or even about whether they could recognize symptoms) was urged to go to their doctor or an emergency room. The Hospital also alerted the surgeons for each of the patients.

The Effect on Respondent's Patients. Not one of the Hospital's patients has become a part of the outbreak. Not one has tested positive for meningitis.

The Hospital has communicated with the Michigan Department of Community Health, the agency here in Michigan collaborating with the CDC and the FDA to investigate the outbreak. The Department followed up on the recall of the NECC medication, and since that time has been monitoring who has gotten sick and where they were treated, tracking the outbreak here in Michigan. **The Department of Community Health has confirmed to the Hospital that no patient treated at Southeast Michigan Surgical Hospital has been counted as a fungal infection case in the NECC outbreak.**

Not one patient has advised the Hospital that a claim is being contemplated or pursued because of the administration of medications from NECC. The Hospital has not received any notice from a lawyer advising that a patient is considering a claim or has joined any existing litigation.

The Subpoena to Southeast Michigan Surgical Hospital. The Subpoena seeks to compel testimony concerning 10 categories of designated subject matter, and to compel production of 21 categories of documents. The testimonial subjects all relate to the means by which the Hospital keeps, organizes, searches, retrieves and stores documents, in electronic and hard copy form. The *duces tecum* listing seeks information concerning whether and how NECC sold medication to the

Hospital, to whom and when it was administered, and what insurance coverage is carried by the Hospital. (The Subpoena is attached as Exhibit 1.)

Shortly after receiving the Subpoena from Plaintiffs' counsel, a further letter from Plaintiffs' counsel arrived, indicating that if the Hospital produces the requested documents, no deposition testimony would be required. (That letter is attached as Exhibit 2.) Plaintiffs' discovery clearly focuses on the Hospital's patient records, medication records, ownership and management of the Hospital, and the Hospital's insurance coverage.

When the Subpoena arrived (along with a press release publicizing the issuance of the subpoena), the Hospital's counsel wrote to the issuing lawyer and noted that no patients of the Hospital have been identified as being involved in the MDL litigation:

We see in your papers no identification of any person treated by the Hospital. We are unable to determine the identity of any patient of the Southeast Michigan Surgical Hospital involved in the MDL action. You have not provided any papers or other evidence of representation of any patient of our client Hospital, represented by the PSC or any lawyer appearing in this case. Information held by our client therefore seems to have no relevance to the claims and defense of the parties to the multi-district litigation.

If you can direct us to a plaintiff in the MDL action who was treated by Southeast Michigan Surgical Hospital with medication from NECP, we will revisit the question.

(Letter to Marc Lipton from Kathryn Humphrey, July 3, 2013, attached as Exhibit 3.) By the morning of July 15, Plaintiffs' counsel had not responded to that letter.

II. APPLICABLE LEGAL STANDARDS

What Law Applies. Other respondents filing motions to quash similar subpoenas in this litigation have set out the authority that allows this MDL Court to issue subpoenas under 28 U.S.C. § 1407(b), and which requires the MDL Court to adjudicate subpoena disputes applying the law of the deponent's district. *United States ex rel. Pogue v Diabetes Treatment Ctrs of Amer., Inc.*, 444 F.3d 462, 468-69 (6th Cir. 2006). Therefore, this Court, in ruling on Southeast Michigan Surgical Hospital's motion to quash, must apply the law of the Sixth Circuit. On the issues involved in this motion, however, the law of the First Circuit mirrors that of the Sixth.

The Discovery Standards for Subpoenas to Non-Parties. These authorities apply to the arguments in Sections III and IV of this Memorandum. They are set out here to avoid repetition.

--Relevance, the foundation of all discovery, is a factor when considering a motion to quash or modify a subpoena under Rule 45. *See Laethem Equip. Co. v. Deere & Co.*, 2007 WL 2873981, at *4 (E.D. Mich. 2007) (noting that the "reach of a subpoena issued pursuant to Fed. R. Civ. P. 45 is subject to the general relevancy standard applicable to discovery under Fed. R. Civ. P. 26(b)(1)").

--Discovery is not unlimited, and “fishing expeditions” are particularly curtailed by courts in the Sixth and First Circuits. The Eastern District of Michigan has ruled that “an overly broad request for discovery which constitutes no more than a fishing expedition will not be allowed.” *Isaac v. Shell Oil Co.*, 83 F.R.D. 428, 431 (E.D. Mich. 1979). *See also United States v. Markwood*, 48 F.3d 969, 982 (6th Cir. 1995) (Federal Rules of Civil Procedure do not grant a party a right to unlimited discovery). The First Circuit does not allow discovery that is unrelated to the claims, simply on speculation that something relevant will turn up. *Ameristar Jet Charter, Inc. v. Signal Composites, Inc.*, 244 F.3d 189, 193 (1st Cir. 2001) (“we will not allow Signal to go on a ‘fishing expedition,’ with the mere ‘hope’ that it will obtain such information.”). The First Circuit limits “over-discovery,” holding that parties “ought not to be permitted to use broadswords where scalpels will suffice, nor to undertake wholly exploratory operations in the vague hope that something helpful will turn up.” *Mack v. Great Atl. & Pac. Tea Co.*, 871 F.2d 179, 187 (1st Cir. 1989).

--The burden on the respondent must be balanced carefully. Under Rule 45, the Court must quash a subpoena that “subjects a person to undue burden.” Fed. R. Civ. P. 45(c)(3)(A). In making this determination, courts are required to balance the need for discovery against the burden imposed on the entity ordered to produce documents.

--The status of an entity as a non-party is a factor that weighs against requiring discovery that burdens the respondent. Both the First and Sixth Circuits note that a non-party has a different status, a different “set of expectations” that are “entitled to special weight.” *Cusumano v. Microsoft Corp.*, 162 F.3d 708, 717 (1st Cir. 1998) (“Although discovery is by definition invasive, parties to a law suit must accept its travails as a natural concomitant of modern civil litigation. Non-parties have a different set of expectations. Accordingly, concern for the unwanted burden thrust upon non-parties is a factor entitled to special weight in evaluating the balance of competing needs.”). *See also In re Smirman*, 267 F.R.D. 221, 223 (E.D. Mich. 2010) (“Whether a burden is undue requires weighing ‘the likely relevance of the requested material . . . against the burden . . . of producing the material.’ Courts also consider one’s status as a nonparty to be a significant factor in the undue-burden analysis.” (quoting *EEOC v. Ford Motor Credit Co.*, 26 F.3d 44, 47 (6th Cir.1994); *N.C. Right to Life, Inc. v. Leake*, 231 F.R.D. 49, 51 (D.D.C. 2005))).

Michigan Law Concerning Privacy of Medical Records. Michigan’s Patient Rights Statute prohibits disclosure of medical information. Under M.C.L. § 20201(2)(b), “Except as otherwise permitted or required under the health insurance portability and accountability act of 1996, Public Law 104-191, or regulations promulgated under that act, 45 CFR parts 160 and 164, *a third party shall not be given a copy of the patient’s or resident’s medical record without prior*

authorization of the patient or resident.” (Emphasis added). The statute provides that: “A patient or resident is entitled to confidential treatment of personal and medical records, and may refuse their release to a person outside the health facility or agency except as required because of a transfer to another health care facility, as required by law or third party payment contract, or as permitted or required under the health insurance portability and accountability act of 1996, Public Law 104-191, or regulations promulgated under that act, 45 CFR parts 160 and 164.”

M.C.L. § 333.20201(2)(c).

III. THE SUBPOENA FOR DOCUMENTS SHOULD BE QUASHED

That portion of the Subpoena seeking documents (electronic and hard copy) should be quashed because:

1. The Subpoena violates the Court’s June 21, 2013, order permitting discovery relevant to claims in this action. There is no connection between Plaintiffs in this litigation and the Hospital, a non-party in this suit. Plaintiffs have identified no patient of Respondent Hospital who has filed suit, joined in the MDL litigation, or given notice of a claim against *any* party relating to the sale of medications by NECC. Not one of the Hospital’s patients has been infected with fungal meningitis from the NECC medication. To the Hospital’s knowledge, no patient of the Hospital has filed suit *in any forum* relating to products manufactured and sold by NECC. Therefore the documents held by the Hospital are not relevant

to the claims of any party in this MDL litigation. The Subpoena exceeds the scope permitted by this Court's Order of June 21, 2013.

2. The documents sought are not relevant. Discovery by subpoena is subject to the general relevance standard for discovery. The Subpoena violates Rule 26. Nor are the document requests reasonably calculated to lead to the discovery of evidence admissible in Plaintiffs' lawsuits:

a. The identity of the Hospital's patients is irrelevant to the claims of those who were treated elsewhere and are now bringing suit.

b. The correspondence from NECC and marketing materials provided by NECC are irrelevant to Plaintiffs' claims. Although they may contain representations made to the Respondent Southeast Michigan Surgical Hospital, they bear no connection to the facilities who treated Plaintiffs. The only relevance in Plaintiffs' suits are representations made to Plaintiffs or to the hospitals that treated them. Statements made to Respondent do not make Plaintiffs' claims more or less likely to be true.

c. Information about insurance coverage of Southeast Michigan Surgical Hospital is irrelevant to the Plaintiffs' claims, because none of the Plaintiffs were ever treated at the Hospital.

d. Documents concerning the ownership, incorporation, management and organization of the Hospital are irrelevant because no Plaintiff was ever a patient there. The Hospital has

no connection to *and no duty to* any Plaintiff. These documents are wholly irrelevant and have no permissible role in discovery of the MDL litigation.

3. The Subpoena is, with respect to Southeast Michigan Surgical Hospital, a wholly improper fishing expedition. The *only* reason for Plaintiffs' counsel to seek the identification of patients who have made no claims, and to demand documents concerning the ownership, management, and insurance of Southeast Michigan Surgical Hospital, is to permit them to contact those patients to fish for additional clients, additional suits, and additional fees. Sixth and First Circuit law denies them the pole and the hook.

4. The Subpoena requires the Hospital to violate Michigan law by disclosing protected and private information. The identity of the Hospital's patients is protected by state law, and cannot be divulged without authorization from the patients themselves. Michigan's Patient Rights Statute prohibits disclosure of that medical information without the patient authorizing it. M.C.L. § 20201(2)(b) and (2)(c). The Subpoena attaches no authorizations from the Hospital's patients.

5. There is no need for patient identification in order to provide the Bankruptcy Court with information necessary to contact potential claimants against Debtor NECC. The Trustee of NECC has proposed to the Bankruptcy Court that

health providers (including Respondent) that purchased medications from NECC be ordered to contact their own patients directly to make those patients aware of the upcoming deadline for filing claims against the Debtor (the “Bar Date”). The Trustee has suggested to the Bankruptcy Court that the various hospitals and clinics send the Bar Date notice directly to their own patients or (at the option of the health provider) provide the names and allow the Trustee to send the notice. (Chapter 11 Trustee’s Motion for An Order (1) Establishing Bar Dates, filed June 28, 2013; *In re New England Compounding Pharmacy, Debtor*, Case No. 12-19882-HJB, United States Bankruptcy Court, District of Massachusetts, Docket #263, Paragraph 38). That proposal by the Trustee acknowledges the privacy of patient identification. Southeast Michigan Surgical Hospital will discharge its obligations to provide that Bar Date Notice if ordered to do so by the Bankruptcy Court, and there is no need for the Hospital to give protected patient identification information to third parties.

6. The Subpoena imposes an undue burden on the Hospital. The steps that must be taken by the Hospital in order to safeguard the privacy interests of its patients far outweighs any utility to any party who might – for whatever reason – wish to have information about the private medical treatment of persons who are not involved in this litigation. The Subpoena does not comply with Rule 45(c)(1):

reasonable steps were not taken “to avoid imposing undue burden or expense” on the Hospital.

7. The Subpoena calls for production of documents protected by the attorney-client privilege. The preservation of that privilege ordinarily requires a respondent to search for, review, and log those privileged documents. But because none of the Hospital’s business records and documents bear any relevance to the MDL Plaintiffs, the requirement – created by Plaintiffs’ having issued a subpoena – that the Hospital search for and log these irrelevant documents is itself an undue burden. Plaintiffs violated Rule 45(c)(1) by not taking reasonable steps to avoid imposing that burden on the Hospital.

8. The Subpoena was not properly served. Rule 45(b)(1) requires that a subpoena be delivered to the person named in the subpoena. The Subpoena directed to the Hospital was sent by certified mail, as evidenced by the last page of Exhibit 1. That does not constitute proper service.

IV. THE SUBPOENA FOR TESTIMONY SHOULD BE QUASHED

That portion of the Subpoena seeking to compel deposition testimony should be quashed because:

1. No patient of the Hospital is involved in this MDL litigation, and no patient of this Hospital is a part of the NECC fungal meningitis outbreak. Thus the

Hospital's documents are not relevant to the existing claims in this litigation. The Subpoena therefore violates the limitations of this Court's order of June 21, 2013.

2. There is likewise no relevance to any testimony concerning how the Hospital keeps its records or searched for documents responsive to this Subpoena. The Subpoena violates Rule 26.

3. The Subpoena does not comply with Rule 45(c)(1) because Plaintiffs took no steps to avoid imposing undue burden on the Hospital. Even though there is no connection between the Hospital and any report of meningitis or other illness from the NECC medication, Plaintiffs wish to have the Hospital select and prepare corporate representatives (something the Notice details in a full page) to testify about its document retention policies, its computer systems, its means of retaining information about patients and medications, and a multitude of other subjects. This burden on the Hospital is unreasonable: it is endless and it has no connection to any Plaintiff in the litigation.

4. The Subpoena does not comply with Rule 45(b)(1) because, in addition to having been sent by certified mail (rather than delivered personally as required by the Rule), it was not accompanied by the required witness fee for attendance at deposition.

**V. RESPONDENT REQUESTS PERMISSION TO ATTEND
TELEPHONICALLY THE JULY 18 STATUS CONFERENCE**

This Court has a standing order permitting counsel to attend conferences telephonically where appropriate. Although the upcoming Status Conference on July 18, 2013, will not likely be short, because of the number of motions and issues to be handled and the multitude of counsel for parties and objectors who may participate, it seems likely that any one counsel's participation will necessarily be brief. The objections filed by many of the Objectors overlap to some extent, and the Court's management of these issues may compress whatever oral argument is permitted.

Respondent requests that the Court permit the Hospital's counsel to attend the conference by telephone, rather than taking on the expense of what will necessarily be a full-day trip from Detroit.

Counsel has reviewed the Court's Standing Order on telephone participation in conferences, is familiar with its requirements, and will observe them if permitted to attend by telephone.

CONCLUSION

For these reasons, Respondent requests that the Court enter an order quashing in its entirety the Subpoena *Duces Tecum*, dated June 21, 2013, directed to Southeast Michigan Surgical Hospital, and that the Court permit counsel for

Respondent to participate in the upcoming Status Conference (to be held on July 18, 2013) by telephone in a manner consistent with the Court's Standing Order on the subject.

Respectfully submitted,

DYKEMA GOSSETT PLLC

By: /s/ Kathryn J. Humphrey
Kathryn J. Humphrey
Michigan Bar No. P32351
Attorneys for Southeast Michigan
Surgical Hospital
400 Renaissance Center
Detroit, MI 48243-1668
(313) 568-6848
khumphrey@dykema.com

Dated: July 15, 2013

CERTIFICATE OF SERVICE

I hereby certify that on July 15, 2013, I caused the foregoing paper to be electronically filed with the Clerk of the Court using the Court's e-filing system, which will send notification of such filing to all counsel of record.

DYKEMA GOSSETT PLLC

By: /s/ Kathryn J. Humphrey
Kathryn J. Humphrey
Michigan Bar No. P32351
Attorneys for Southeast Michigan Surgical
Hospital
400 Renaissance Center
Detroit, MI 48243-1668
(313) 568-6848
khumphrey@dykema.com